APR - 9 2001

K003494

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor: Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Submitted on behalf of Walter Lorenz

Manufacturer: Biomet Manufacturing Corp.
56 East Bell Drive
Warsaw Indiana 46582

Proprietary Name: Mimix™ Bone Replacement System

Common Name: calcium phosphate cement

Classification Name: Implant, endosseous for bone filling and/or reconstruction

Device Classification: Class III

Device Product Code: 76LYC

Device Description:
The Mimix™ Bone Replacement System is packaged as separate, pre-measured powder and liquid components. The two components are designed to be mixed intraoperatively to produce a homogenous paste, which can then be applied to bone gaps or defects.

The Mimix™ Bone Replacement System is comprised of a calcium phosphate powder and a liquid component. When mixed, the powder and liquid combine to form a homogenous paste.

The Mimix™ Bone Replacement System is a non-toxic, non-mutagenic, non-hemolytic, and non-pyrogenic biocompatible material. Mechanical testing determined the material has adequate strength for the intended use.

Indications for Use:

Mimix™ Bone Replacement System is indicated for use in the following dental and/or oral surgical procedures:

1. Alveolar ridge augmentation/reconstruction
2. Filling of resection defects in benign bone tumor, bone cysts, or other defects in the alveolar ridge or wall
3. Filling of periodontal bone pockets in the jaw (granules I)
4. Filling bone defects after apicetomy
5. Filing alveoli after tooth extraction

This product should not be used in non-periodontal mandibular applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2001

Ms. Michelle L. McKinley
Regulatory Specialist
Biomet, Incorporated
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K003494
Trade Name: Mimix™ Bone Replacement System
Regulatory Class: III
Product Code: LYC
Dated: March 7, 2001
Received: March 8, 2001

Dear Ms. McKinkley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If Known): K003494

Device Name: Mimix™ Bone Replacement System

Indications for Use:

Mimix™ Bone Replacement System is indicated for use in the following dental and/or oral surgical procedures:

1. Alveolar ridge augmentation/reconstruction
2. Filling of resection defects in benign bone tumor, bone cysts, or other defects in the alveolar ridge or wall
3. Filling of periodontal bone pockets in the jaw
4. Filling bone defects after apicetomy
5. Filing alveoli after tooth extraction

This product should not be used in non-periodontal mandibular applications.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003494